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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,231	12/29/2000	Richard N. Ellson	7610-0040	8767

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,231	ELLSON ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-58 and 81-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,19-49,54,56, 81 and 84* is/are rejected.

7)☒ Claim(s) *82 and 83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/29/00 & 7/31/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 05/23/2005 is acknowledged and entered. Claims 1, 5, 54, and 56 have been amended.

2. Claims 1, 6-7, 9, 24, 54, and 56 amended by the amendment filed on 1/29/2004.

3. Claims 1, 3, 54, 56 amended and Claims 81-84 were added by the amendment filed on 7/28/2003.

4. Claims 2, and 59-80 were canceled by the amendment filed on 3/3/2003.

5. Claims 1, 3-58, and 81-84 are pending.

Election/Restrictions

6. Claims 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a ***nonelected invention***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/18/2002.

7. Applicant has elected the following species for the elected invention (Claims 1-49, 54-58, and 81-84) in the reply filed on 9/18/2002:

a. Species (1) (Claims 6-10), temperature.

8. Claims 11-18, 55, 57, 58 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/18/2002.

9. Claims 1, 3-10, 19-49, 54, 56, and 81-84 are under consideration in this Office Action.

Maintained Rejection(s)

Claim Objections

10. Claim 82 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 83.

Claim Rejections - 35 USC § 112

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 81, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455).

15. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093).

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 1, 3-10, 19-37, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617).

18. Claims 1, 6, and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. (*Proc. Natl. Acad. Sci.*, **1992**, 89(12):5381-5383) and Wang et al. (US Patent 5,922,617).

Response to Arguments

19. Applicant's argument directed to the objection of claim 82 under 37 CFR 1.75 as being a substantial duplicate of claim 83 has been fully considered but they are not persuasive for the following reasons.

> *Claim 82 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 83. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 82 recites wherein the indicator*

structure is comprised of a single-stranded oligonucleotide having defined sequences prehybridized to a labeled target. The labeled target is interpreted as a complementary single-stranded oligonucleotide with a label and the term "prehybridized" is interpreted as already formed 'duplex', i.e. double-stranded oligonucleotide. Claim 83 recites wherein the indicator structure is comprised of a double-stranded oligonucleotide having one labeled strand. Thus Claim 82 is a substantial duplicate of claim 83.

Applicant contends that claim 82 is not a substantial duplicate of claim 83 because "*claim 83 requires that the labeled strand, which has hybridized to the indicator be a target, whereas claim 82 does not contain any requirement that either strand of the double-stranded nucleotide be a target*". Thus, claim 82 is not a substantial duplicate of claim 83.

Applicant's arguments are not convincing since claim 82 is a substantial duplicate of claim 83 because claim 82 recite that '*the indicator structure is comprised of a single-stranded oligonucleotide having defined sequences prehybridized to a labeled target*', i.e. a double stranded oligonucleotide with a label, and that label is on one of the single-stranded oligonucleotide. Claim 83 recite that '*the indicator structure is comprised of a double-stranded oligonucleotide having one labeled strand*', i.e. a double stranded oligonucleotide with a label, and that label is on one of the single-stranded oligonucleotide. How the single-stranded oligonucleotide with the label is designated (e.g. a 'target' or a complementary strand) does not change the overall structure of the claimed indicator, which is a double stranded oligonucleotide with a label on one of the single-stranded oligonucleotide. Thus, claim 82 is a substantial duplicate of claim 83, and the objection is maintained.

20. Applicant's arguments directed to the rejection under 35 U.S.C. 112, second paragraph, as being indefinite for claims 81 and 84 have been fully considered but they are not persuasive for the following reasons.

Claims 81, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 81 is vague and indefinite because it is unclear as to the ability of the indicator structure to exhibit a response wherein the indicator structure is nucleotidic. It is unclear what constitutes the metes and bounds as to the 'type' of "detectable response" that is exhibits by the indicator structure when expose to the condition and lasted for at least one minute after removing from the condition as claimed in claim 1, i.e. what response is being 'exhibits' by a nucleotide when expose to the condition and lasted for at least one minute after removing from the condition? Thus claim 81 is vague and indefinite.

b) Claim 84 is vague and indefinite because it is unclear as to the ability of the indicator structure to exhibit a response wherein the indicator structure is wax. It is unclear what constitutes the metes and bounds as to the 'type' of "detectable response" that is exhibits by the indicator structure when expose to the condition and lasted for at least one minute after removing from the condition as claimed in claim 1, i.e. what response is being 'exhibits' by a wax when expose to the condition and lasted for at least one minute after removing from the condition? Thus claim 81 is vague and indefinite.

Applicant argues that both claims 81 and 84 are not indefinite because '*Nucleotidic materials (e.g., oligonucleotides and polynucleotides, single or double stranded) exhibit well-known responses to a variety of conditions such as temperature, pH, and the presence of reagents. They can, for example, denature or cross-link. Double- stranded oligo- and polynucleotides can dissociate to become single stranded. Single-stranded oligo- and polynucleotides can hybridize to become double stranded. Many of these responses are not reversible by removal of the condition; others, while reversible, may involve a return of the nucleotidic material to its prior state at a rate such that the response remains detectable for one minute (or longer). In light of these facts, a person of skill in the art would understand what it means for a nucleotidic indicator structure to exhibit a response to being exposed to a condition. Claim 81 is not indefinite. For similar reasons, claim 84 is not indefinite*'

Applicant's arguments are not convincing since both claims 81 and 84 are indefinite. First, claim 84 claimed that the indicator structure is wax and claim 81 claimed that indicator structure is nucleotidic. The structurally and functionally the nucleotidic compound is distinct from that of the wax compound. Thus, applicant argument that the wax compound response to the condition such as '*temperature, pH, and the presence of reagents*' would produce the same

'result' as the nucleotidic compound is confusing since applicant has not provided and evidence that the nucleotidic compound and the wax compound are structurally and functionally identical. The indefinite rejection with regard to claim 84 is maintained.

Second with regard to the nucleotidic compound, applicant indicated that some of the conditions such as '*temperature, pH, and the presence of reagents*' are reversible such that '*a return of the nucleotidic material to its prior state at a rate such that the response remains detectable for one minute (or longer)*'. However, it is unclear as to which of the conditions that applicant referring to that results in '*a return of the nucleotidic material to its prior state at a rate such that the response remains detectable for one minute (or longer)*'. For example, in general double-stranded oligonucleotides denature at about 90 °C, and it anneal (reformation of the double-stranded oligonucleotide) at about 50-60 °C. Thus, by removing the denatured double-stranded oligonucleotide from the condition of 90 °C would not 'return' the denatured double-stranded oligonucleotide to its prior state, i.e. the double-stranded form, such that a detectable response is detected. Therefore, both claims 81 is indefinite since a person of skill in the art would not understand what it means for '*a nucleotidic indicator structure to exhibit a response to being exposed to a condition*'.

Therefore, both claims 81 and 84 are indefinite, and the rejections are maintained.

21. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455) for claims 54 and 56 were considered but they are not persuasive for the following reasons.

> *Claims 54, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (US Patent 5,770,455).*

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. With regard to claim 54 the molecular moieties are nucleotidic molecular probes.

Cargill et al. disclose labeled libraries of random oligomers (device) (see e.g. Abstract; col. 1, lines 66 to col. 2, line 4; col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (see e.g. col. 7, lines 4-19; col. 7, line 53 to col. 8, line 15; col. 8, line 44-57; col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The synthesis support has a plurality of oligomer library members attached (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The oligomers include polynucleotides (see. e.g. col. 8, lines 18-40; col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (see e.g. col. 12, lines 14-45; col. 14, lines 37-52). Therefore, the device of Cargill et al. anticipates the presently claimed device.

Applicant alleges that the device of Cargill et al. does not anticipate the presently claimed invention because the identifier tag of Cargill et al. does not anticipate the presently claimed indicator since the presently claimed indicator produces '*detectable response to being exposed to an environmental condition*'. Thus, the device of Cargill et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the device of Cargill et al. does anticipate the presently claimed invention because the limitation that the indicator produces 'detectable response to being exposed to an environmental condition' is a functional limitation of the indicator. The claimed indicator structural feature is that it is not a single stranded oligonucleotide if the probes/molecular moieties are single stranded oligonucleotides. The identifier tag of Cargill et al. are not single-stranded oligonucleotides (see e.g. col. 7, lines 4-15; col. 21, lines 24-32). Thus, the identifier tag of Cargill et al. anticipate the structural limitation of the claimed indicator, and the functional limitation of the indicator, i.e. 'detectable response to being exposed to an environmental condition' is presumed to be inherent. See MPEP § 2112.01. MPEP § 2112.01 states that:

II. >< COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Therefore, the device of Cargill et al. does anticipate the presently claimed invention, and the rejection is maintained.

22. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093) for claim 56 were considered but they are not persuasive for the following reasons.

Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Bioarray Solutions LLC ("Bioarray") (WO 98/53093).

The instant claim recites a device that comprises a substrate, molecular moieties, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region and the molecular moieties are attached to the probe region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides.

Bioarray discloses labeled libraries of beads (device) (see e.g. Abstract; pg. 7, line 16-30). The libraries of beads comprise beads (substrate), color codes (integrated indicator), and compounds (molecular moieties) (see e.g. pg. 17, lines 1-11; fig. 3). The bead comprises different areas wherein the color codes and compounds are attached (probe region and indicator region). The color codes would contain informations of events that occur with the compounds such as target binding and environmental monitoring (see e.g. pg. 17, line 14-27; pg. 20, lines 7-27). Therefore, the device of Bioarray anticipates the presently claimed device.

Applicant contends that the device of Bioarray does not anticipate the presently claimed invention because the color codes of Bioarray does not anticipate the presently claimed indicator since the presently claimed indicator produces '*detectable response to being exposed to an environmental condition*'. Thus, the device of Bioarray does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the device of Bioarray does anticipate the presently claimed invention because the limitation that the indicator produces 'detectable response to being exposed to an environmental condition' is a functional limitation of the indicator. The claimed indicator structural feature is that it is not a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. The color codes of Bioarray are not single-stranded oligonucleotides (see e.g. pg. 9, lines 16-21). Thus, the color codes of Bioarray anticipate the structural limitation of the claimed indicator, and the functional limitation of the indicator, i.e. 'detectable response to being exposed to an environmental condition' is presumed to be inherent. See MPEP § 2112.01. MPEP § 2112.01 states that:

> *II. >< COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES*
>
> "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Therefore, the device of Bioarray does anticipate the presently claimed invention, and the rejection is maintained.

23. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617) for claims 1, 3-10, 19-37, and 47-49 were considered but they are not persuasive for the following reasons.

> *Claims 1, 3-10, 19-37, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (US Patent 5,770,455) and Wang et al. (US Patent 5,922,617).*
>
> *The instant claim 1 recites a device that comprises a substrate, a plurality of different molecular probes, and an integrated indicator. The substrate comprises a probe region and an indicator region. The integrated indicator is attached to the indicator region. The indicator exhibits the detectable response for at least one minute after removing the device from the condition and is not*

a single stranded oligonucleotide if the molecular moieties are single stranded oligonucleotides. The different molecular probes are attached to the probe region and interact with a corresponding target.

Cargill et al. disclose labeled libraries of random oligomers (device) (see e.g. Abstract; col. 1, lines 66 to col. 2, line 4; col. 9, line 64 to col. 10, line 8). The labeled libraries of random oligomers comprise a synthesis support (substrate), an identifier tag (integrated indicator), and an oligomer library member (molecular moieties) (see e.g. col. 7, lines 4-19; col. 7, line 53 to col. 8, line 15; col. 8, line 44-57; col. 11, lines 18-33; fig. 7). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The synthesis support has a plurality of oligomer library members attached (see e.g. col. 11, lines 51-54; col. 12, lines 14-45; col. 14, lines 37-52; fig. 7). The oligomers include polynucleotides (see. e.g. col. 8, lines 18-40; col. 13, lines 27-48). The identifier tag would contain information of transformation events such as changes in temperature (see e.g. col. 12, lines 14-45; col. 14, lines 37-52).

The device of Cargill et al. differs from the presently claimed invention by failing to include a plurality of different molecular probes on the surface of the substrate.

Wang et al. disclosed a device in which the microarray would contain 10 or more different probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of different molecular probes on the surface of the substrate as taught by Wang et al. for the device of Cargill et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the device of Cargill et al. for the advantage of detecting multiple analytes since both Cargill et al. and Wang et al. disclose beads that are encoded with a binary code (Cargill: col. 10, lines 17-26; Wang: col. 7, lines 10-20). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Cargill et al. and Wang et al. because Wang et al. suggest that the number of probes on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component.

Applicant alleges that the device combination of Cargill et al. and Wang et al. is not obvious over the presently claimed device because 1) the identifier tag of Cargill et al. does not anticipate the presently claimed indicator since the presently claimed indicator produces '*detectable response to being exposed to an environmental condition*'; 2) Cargill et al. do not disclose that the condition allows for target-probe interaction of claim 5; 3) Cargill et al. do not disclose that the targets represent portions of a single molecule of claim 47; and 4) Cargill et al. do not disclose that the targets represent portions of a single cell of claim 48. Thus, the device combination of Cargill et al. and Wang et al. is not obvious over the presently claimed device.

Applicant's arguments are not convincing since the device combination of Cargill et al. and Wang et al. is obvious over the presently claimed device.

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Second, the limitation that the indicator produces 'detectable response to being exposed to an environmental condition' is a functional limitation of the indicator. The claimed indicator structural feature is that it is not a single stranded oligonucleotide if the probes are single stranded oligonucleotides. The identifier tag of Cargill et al. are not single-stranded oligonucleotides (see e.g. col. 7, lines 4-15; col. 21, lines 24-32). That is the identifier tag of Cargill et al. anticipate the structural limitation of the claimed indicator, and the functional limitation of the indicator, i.e. 'detectable response to being exposed to an environmental condition', is presumed to be inherent. See MPEP § 2112.01. MPEP § 2112.01 states that:

> *II. >< COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES*
>
> "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Therefore, the identifier tag of Cargill et al. anticipate the structural limitation of the claimed indicator.

Third, Cargill et al. do disclose a) the condition allows for target-probe interaction of claim 5 (see e.g. col. 7, lines 53-62; col. 26, lines 46-58); b) the targets represent portions of a

single molecule of claim 47 (see e.g. col. 26, lines 46-58); and c) the targets represent portions of a single cell of claim 48 (see e.g. col. 26, lines 46-58).

Therefore, the device combination of Cargill et al. and Wang et al. is obvious over the presently claimed device, and the rejection is maintained.

24. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Brenner et al. (*Proc. Natl. Acad. Sci.*, **1992**, 89(12):5381-5383) and Wang et al. (US Patent 5,922,617) for claims 1, 6, and 81-82 were considered but they are not persuasive for the following reasons.

> *Claims 1, 6, and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner et al. (Proc. Natl. Acad. Sci., **1992**, 89(12):5381-5383) and Wang et al. (US Patent 5,922,617).*
>
> *Brenner et al. disclose a combinatorial library of encoded compound (refers to the presently claimed device) and the method of two alternating parallel combinatorial syntheses wherein the genetic tag is chemically link to the chemical structure being synthesized (see e.g. Abstract; pg. 5381, right col., lines 30-54; pg. 5382, right col., line 34 to picture at top of pg. 5183). The combinatorial library of encoded compound comprises a genetic tag (refers to the presently claimed indicator structure), a solid support (refers to the presently claimed substrate), and peptide sequences (refers to the presently claimed probe) (see e.g. pg. 5382, right col., line 34 to picture at top of pg. 5183). The genetic tag is single-stranded oligonucleotide (refers to instant claims 81-82), which are detected by PCR after the combinatorial library of encoded compound is exposed to a binding assay (see e.g. pg. 5381, right col., lines 54-56; pg. 5383, left col., line 47 to pg. 5383, right col., line 34). The synthesis support comprises different areas wherein the identifier tag and oligomer library member are attached (probe region and indicator region) (see e.g. pg. 5382, right col., lines 41-44; picture at top of pg. 5183).*
>
> *The combinatorial library of encoded compound of Brenner et al. differs from the presently claimed invention by failing to include a plurality of different molecular probes on the surface of the substrate.*
>
> *Wang et al. disclosed a device in which the microarray would contain 10 or more different probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).*
>
> *It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a plurality of different molecular probes on the surface of the substrate as taught by Wang et al. in the combinatorial library of encoded compound of Brenner et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the combinatorial library of encoded compound of Brenner et al. for the advantage of detecting multiple analytes since both Brenner et al. and Wang et al. disclose beads that are encoded with a binary code. (Brenner: pg. 5382, right col., lines 41-44; picture at top of pg. 5183; Wang: col. 7, lines 10-20). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Brenner et al. and Wang et al. because Wang et al. suggest that the number of probes on an*

array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (Wang: col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component.

Applicant argues that the device combination of Brenner et al. and Wang et al. is not obvious over the presently claimed device because the identifier tag of Brenner et al. does not anticipate the presently claimed indicator since the presently claimed indicator produces '*detectable response to being exposed to an environmental condition*'. Thus, the device combination of Brenner et al. and Wang et al. is not obvious over the presently claimed device.

Applicant's arguments are not convincing since the device combination of Brenner et al. and Wang et al. is obvious over the presently claimed device.

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Second, the limitation that the indicator produces 'detectable response to being exposed to an environmental condition' is a functional limitation of the indicator. The claimed indicator structural feature is that it is not a single stranded oligonucleotide if the probes are single stranded oligonucleotides. The genetic tag of Brenner et al. are not single-stranded oligonucleotides (see e.g. pg. 5381, right col., lines 54-56; pg. 5383, left col., line 47 to pg. 5383, right col., line 34). That is the genetic tag of Brenner et al. anticipate the structural limitation of the claimed indicator, and the functional limitation of the indicator, i.e. 'detectable response to being exposed to an environmental condition', is presumed to be inherent. See MPEP § 2112.01. MPEP § 2112.01 states that:

II. >< COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Therefore, the genetic tag of Brenner et al. anticipate the structural limitation of the claimed indicator.

Therefore, the device combination of Brenner et al. and Wang et al. is obvious over the presently claimed device, and the rejection is maintained.

25. Applicant requested clarification of the indication of the allowable subject matter. However upon further reconsideration, the indication of allowable subject matter is withdrawn.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
August 20, 2005

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